

EXHIBIT 4

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

| | | |
|---|---|----------------------------------|
| IN RE: NATIONAL PRESCRIPTION |) | MDL 2804 |
| OPIATE LITIGATION |) | |
| |) | Case No. 1:17-md-2804-DAP |
| This document relates to: |) | |
| |) | Judge Dan Aaron Polster |
| <i>County of Webb v. Purdue Pharma, L.P. et al.</i> |) | |
| Case No. 1:18-op-45175-DAP (N.D. Ohio) |) | |
| |) | |
| <i>Employer-Teamsters Local Nos. 175 & 505</i> |) | |
| <i>Health & Welfare Fund, et al. v. Purdue</i> |) | |
| <i>Pharma L.P., et al.</i> |) | |
| Case No. 1:18-op-45446-DAP (N.D. Ohio) |) | |

DECLARATION OF JOANNE CICALA
IN SUPPORT OF JOINT MOTION FOR PRELIMINARY INJUNCTIVE RELIEF

I, Joanne Cicala, declare the following:

1. I am the managing partner at The Cicala Law Firm PLLC and counsel of record for Plaintiff County of Webb, Texas (“Webb”) in the above-captioned matter. I am a member in good standing of the State Bars of Texas, New York and New Jersey. I submit this declaration in support of the Joint Motion for Preliminary Injunctive Relief filed by Webb and Plaintiffs Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund, Employer-Teamsters Local Nos. 175 & 505 Retiree Health & Welfare Fund (collectively “Plaintiffs”). I have personal knowledge of the following facts.

2. Impacting every geographic region of this Country, more than 134 Americans are still dying on a daily basis from addiction connected to an opioid prescription.¹

¹ See NIH, *Overdose Death Rates*, NATIONAL INSTITUTE ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (estimating more than 49,000 opioid related deaths in 2017).

3. This Honorable Court has before it, as defendants in the above-captioned cases, three companies who control the pharmacy benefits for over 238 million Americans: CVS Caremark (“Caremark”), Express Scripts and OptumRx.²

4. These pharmacy benefit managers (“PBMs”) have the ability – right now – through their drug formularies and plan design – to abate the flow of opioids into our communities and to improve access to opioid reversal agents and addictive treatment medications. With a few edits to their quantity limits, prior authorization requirements and step-therapies, the PBMs could immediately and dramatically reduce the number of improper opioid prescriptions leading to addiction and death.

5. This Declaration seeks to support the entry of an order directing these middlemen in the prescription drug delivery system – the gatekeepers to nearly every drug that is dispensed at a pharmacy and reimbursed by private and public payors (including Medicare and Medicaid) – to immediately close their gates to unnecessary opioid scripts and improper utilization, and to remove barrier to reversal and treatment drugs.

6. Importantly, the relief sought will not prevent the appropriate prescribing of opioids to patients who genuinely need them.

7. The relief sought will not disturb any operative Case Management Order, ruling of a special master or the schedule for the bellwether trials.

8. The relief sought will merely install barriers to improper entry; safeguards consistent with the U.S. Centers for Disease Control and Prevention’s *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* that the PBMs themselves embrace, and current scientific literature.

² NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, *PBM Resources*, <http://www.ncpanet.org/advocacy/the-tools/pbm-resources> (last visited Aug. 28, 2018).

9. Attached as Exhibit A are the following collection of communications to the Court and/or the PEC regarding the PBMs' unique role in the opioid crisis: (i) letter dated January 26, 2018 from Joanne Cicala and Kevin Sharp to Plaintiffs' Co-Leads; (ii) letter dated January 31, 2018 from Joanne Cicala to Honorable Judge Dan A. Polster (ECF No. 108); (iii) letter dated March 6, 2018 from Joanne Cicala to Honorable Judge Dan A. Polster (ECF No. 168); and (iv) letter dated March 16, 2018 from Joanne Cicala to Special Masters Cohen, McGovern and Yanni.

10. Attached as Exhibit B is the U.S. Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY AND MORTALITY WEEKLY REPORT 1 (2016) ("CDC Guideline").

11. Attached as Exhibit C is a four-page summary of the CDC Guideline entitled *CDC Guideline for Prescribing Opioids for Chronic Pain* ("Guideline Summary"), available on the CDC website along with the CDC Guideline at https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.

12. Attached as Exhibit D is an opioid guidelines fact sheet published by the CDC on its website. See CDC, *Guideline for Prescribing Opioids for Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf ("Guideline Fact Sheet").

13. Attached as Exhibit E is Thomas R. Frieden, M.D., M.P.H., and Debra Houry, M.D., M.P.H., *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, NEW ENGLAND JOURNAL OF MEDICINE PERSPECTIVE, Apr. 21, 2016.

14. Attached as Exhibits F-1 and F-2 are the following documents published by Caremark regarding its formularies and formulary development:

- (a) Exhibit F-1: CVS Health, *Formulary Management*, <https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management>; and

(b) Exhibit F-2: CVS Caremark, *Formulary Development and Management at CVS Caremark*, Mar. 25, 2018, <https://www.caremark.com/portal/asset/FormDevMgmt.pdf>.

15. Attached as Exhibits G-1 – G-6 are the following examples of Caremark’s standard formularies for 2018:

(a) Exhibit G-1: Performance Drug List – Standard Control (July 2018) and Prescribing Guide;

(b) Exhibit G-2: Performance Drug List – Standard Opt-Out (July 2018) and Prescribing Guide;

(c) Exhibit G-3: Advanced Control Formulary (July 2018);

(d) Exhibit G-4: Value Formulary *Effective as of 07/01/2018*;

(e) Exhibit G-5: SilverScript Medicare Choice Formulary;³ and

(f) Exhibit G-6: SilverScript Medicare Plus Formulary.

16. Attached as Exhibits H-1 – H-3 are the following documents published by Caremark regarding its opioid utilization program:

(a) Exhibit H-1: CVS Health, *The Balancing Act, Helping Ensure Appropriate Access to Opioids While Minimizing Risk*, INSIGHTS FEATURE, Feb. 28, 2017, <https://payorsolutions.cvshealth.com/insights/balancing-act>;

(b) Exhibit H-2: CVS Caremark, *CVS Caremark Opioid Quantity Limits Pharmacy Reference Guide*, Jan. 2018, <https://www.caremark.com/portal/asset/OpioidReferenceGuide.pdf>; and

³ SilverScript is a Prescription Drug Plan with a Medicare contract offered by SilverScript Insurance Company, a Tennessee corporation, and a wholly owned subsidiary of the CVS Health Corporation, a PBM defendant named in the above captioned cases.

(c) Exhibit H-3: CVS Health, *Utilization Management Strategies to Address the Opioid Crisis*, Feb. 28, 2018, <https://cvshealth.com/thought-leadership/utilization-management-strategies-to-address-the-opioid-crisis>.

17. Attached as Exhibits I-1 – I-3 are the following documents published by Express Scripts regarding its formularies and formulary development:

(a) Exhibit I-1: Express Scripts, *The Value of Active Pharmacy Management: Express Scripts 2018 National Preferred Formulary*, 2018, <https://www.multivu.com/players/English/81495241-express-scripts-national-preferred-formulary-2018/>;

(b) Exhibit I-2: Express Scripts, *Express Scripts 2017 Annual Report*, <https://expressscriptsholdingco.gcs-web.com/static-files/76a9c03e-2e6b-4f6b-80de-fe80d4ebc826>; and

(c) Exhibit I-3: Express Scripts, *Smart Formulary Management*, Jan. 2, 2014, <http://lab.express-scripts.com/lab/insights/drug-options/smart-formulary-management>.

18. Attached as Exhibits J-1 – J-5 are the following examples of Express Scripts' standard formularies for 2018:

- (a) Exhibit J-1: 2018 Express Scripts National Preferred Formulary;
- (b) Exhibit J-2: 2018 National Preferred Formulary Exclusions;
- (c) Exhibit J-3: Express Scripts Medicare (PDP) 2018 Formulary (Saver Plan);
- (d) Exhibit J-4: Express Scripts Medicare (PDP) 2018 Formulary (Value Plan);

and

(e) Exhibit J-5: Express Scripts Medicare (PDP) 2018 Formulary (Choice Plan).

19. Attached as Exhibits K-1 – K-4 are documents published by Express Scripts regarding its opioid management program:

- (a) Exhibit K-1: Express Scripts, *Putting the brakes on the opioid epidemic*, <https://my.express-scripts.com/opioids.html>;
 - (b) Exhibit K-2: Express Scripts list of programs and associated fees.
 - (c) Exhibit K-3: Nicholas Hamm, *Express Scripts Limits Opioid Prescriptions*, DRUG TOPICS, Aug. 17, 2017, <http://www.drugtopics.com/clinical-news/express-scripts-limits-opioid-prescriptions>; and
 - (d) Exhibit K-4: Express Scripts, *Express Scripts Significantly Reduces Inappropriate Selection and Excessive Dispensing of Opioids for New Patients*, Jan. 11, 2018, <http://lab.express-scripts.com/lab/insights/drug-safety-and-abuse/reducing-inappropriate-selection-and-excessive-dispensing-of-opioids>.
20. Attached as Exhibit L is OptumRx, *OptumRx: Driving Smarter Health Care Connections*, https://www.optum.com/content/dam/optum/resources/brochures/Rx/OptumRxFactSheet_Final.pdf.
21. Attached as Exhibits M-1 – M-6 are the following examples of OptumRx’s standard formularies for 2018:
- (a) Exhibit M-1: 2018 Essential Health Benefits Base Formulary;
 - (b) Exhibit M-2: 2018 Essential Health Benefits Enhanced Formulary;
 - (c) Exhibit M-3: 2018 Generic Centric Formulary;
 - (d) Exhibit M-4: 2018 Premium Formulary;
 - (e) Exhibit M-5: 2018 Select Formulary; and
 - (f) Exhibit M-6: 2018 Medicare Part D Comprehensive Formulary.
22. Attached as Exhibits N-1 – N-4 are the following documents published by OptumRx regarding its opioid management program:

(a) Exhibit N-1: Optum, *OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients*, Aug. 22, 2017, <https://www.optum.com/about/news/optumrx-risk-management-program-leads-to-better-outcomes.html>;

(b) Exhibit N-2: OptumRx, *Confronting the Opioid Epidemic*, 2018, <https://www.optum.com/resources/library/opioid-e-book.html?s3=rxopioid>; and

(c) Exhibit N-3: OptumRx, *OptumRx Opioid Risk Management*, 2018, <https://www.accesskent.com/Benefits/pdf/Opioid-Brochure.pdf>.

23. Attached as Exhibits O-1 – O-9 are the following articles:

(a) ALABAMA: Bridgette Marshall, wife of Alabama Attorney General Steve Marshall, became dependent on opioids that were prescribed to her for treating migraines she had suffered since childhood. After years of grappling with depression, anxiety, and chronic pain from digestive disorders and migraines, she committed suicide on June 24, 2018. See Kim Chandler, *Alabama's Top lawyer shares his grief about wife's suicide*, AP NEWS, June 28, 2018, <https://apnews.com/6781722719de44eab86d24027fbd1a56>, attached as Exhibit O-1.

(b) CALIFORNIA: A 34-year old woman received 300 pills within a twelve-month period, including hydrocodone, oxycodone, and codeine, along with other agents such as sleeping pills, anti-anxiety medications, and muscle relaxants. All of these pills were derived from 54 prescriptions, written by 36 different doctors and dispensed by 21 different pharmacies. The woman died in San Diego from an overdose of oxycodone. This is but one of 254 prescription drug deaths in 2013 documented by Dr. Roneet Lev in a project titled "Death Diaries." See Kristina Davis, *'Death Diaries' reveal lessons about prescription drug epidemic*, THE SAN DIEGO UNION-TRIBUNE, Jan. 6, 2018,

<http://www.sandiegouniontribune.com/news/public-safety/sd-me-death-diaries-20170106-story.html>, attached as Exhibit O-2.

(c) ILLINOIS: During a course of over prescription to treat chronic knee pain, Linda Svanstrom, 56, became addicted to opioids. She died from an overdose on February 7, 2017. See Katie Kim, *Family Sues Suburban Hospital After Grandmother Dies from Prescription Drug Overdose*, NBC, May 11, 2018, <https://www.nbcchicago.com/news/local/Family-Sues-Suburban-Hospital-After-Grandmother-Dies-of-Overdose-482416861.html>, attached as Exhibit O-3.

(d) NEW YORK: Katie-Lynn Scheidt, a certified nurse's aide, became addicted to heroin after being prescribed pain pills in 2011. After leaving one rehab center and while awaiting admittance into another, Nurse Scheidt died from a heroin overdose in Saratoga Springs, N.Y. Her father, a retired NY State Trooper, is now telling her story. See Lauren Stanforth, *Retired NY state trooper avenges daughter's death*, HOUSTON CHRONICLE, Feb. 13, 2018, <https://www.chron.com/local/article/Saratoga-County-ex-cop-aveneges-daughter-s-death-12609988.php?ipid=hpctp>, attached as Exhibit O-4.

(e) OHIO: Alex Gurvis, a former military police officer in the National Guard, was introduced to opioids in 2005 when he was prescribed OxyContin to treat injuries he sustained while on active duty. Officer Gurvis became addicted and the OxyContin proved a gateway to heroin. Officer Gurvis ultimately died of an overdose of both illegal and prescription drugs. See Sandra Gurvis, *Health: A Mother's Story about the Opioid Crisis*, COLUMBUS MONTHLY, Feb. 27, 2018, <http://www.columbusmonthly.com/lifestyle/20180227/health-mothers-story-about-opioid-crisis>, attached as Exhibit O-5.

(f) SHINNECOCK INDIAN NATION, NEW YORK: Kyle Fox was prescribed OxyContin to treat the pain of a basic tooth extraction. He was later found dead

in his car after he suffered an overdose from fentanyl disguised as OxyContin. *See* Beth Young, *Opioid Crisis: Sharing Stories and Tears, In Hopes of Destigmatizing Addiction*, EAST END BEACON, May 15, 2018, <https://www.eastendbeacon.com/opioid-crisis-sharing-stories-and-tears-in-hopes-of-destigmatizing-addiction>, attached as Exhibit O-6.


(g) TENNESSEE: Heather Baltz became addicted to heroin after running out of pain medication for a gallbladder surgery in 2014. In February of 2018, she died from a heart infection caused by a contaminated needle she used to inject heroin. *See* Anita Wadhvani, *1 family, 3 deaths: Couple must pick up pieces—again—after opioids’ destruction*, NASHVILLE TENNESSEAN, June 30, 2018, <https://www.tennessean.com/story/news/2018/07/01/opioid-epidemic-todd-harrell-3-door-down-heroin-deaths/726386002>, attached as Exhibit O-7.

(h) VIRGINIA: Following a 2012 prescription for opioid cough syrup for pain, Tess Henry, a Virginia woman struggled with addiction and rehab attempts for six years until she was murdered. Her remains were found in a Las Vegas dumpster. *See* Beth Macy, *‘I Am Going to Die if I Keep Living the Way I am.’ She was Right.*, N.Y. TIMES, July 20, 2018, <https://www.nytimes.com/2018/07/20/opinion/sunday/opioid-addiction-treatment.html>, attached as Exhibit O-8.

(i) WEST VIRGINIA: Notwithstanding signs of suspicious prescription activity, Timothy Jason Lewis became addicted to opioids stemming from prescriptions he received for oxycodone and methadone in 2014. He died of an overdose on May 4, 2017. *See* Lacie Pierson, *Mother sues HOPE Clinic, pharmacies for son’s overdose death*, WEST VIRGINIA GAZETTE, July 5, 2018, https://www.wvgazettemail.com/news/cops_and_courts/mother-sues-hope-clinic-pharmacies-for-son-s-overdose-death/article_33268904-136e-5e3b-a271-f6ac80df29_67.html, attached as Exhibit O-9.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Date: September 14, 2018

By: 

Joanne Cicala